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BSI Standards Publication

Surgical clothing and drapes — Requirements and test methods

Part 1: Surgical drapes and gowns

bsi.

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National foreword

This British Standard is the UK implementation of EN 13795-1:2025. It supersedes BS EN 13795-1:2019, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/205, Non-active medical devices.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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UK Government is responsible for legislation. For information on legislation and policies relating to that legislation, consult the relevant pages of www.gov.uk.

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Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 28 February 2025.

Amendments/corrigenda issued since publication

Date	Text affected

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EUROPEAN STANDARD **EN 13795-1**

NORME EUROPÉENNE

EUROPÄISCHE NORM

January 2025

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English Version

Surgical clothing and drapes - Requirements and test methods - Part 1: Surgical drapes and gowns

Vêtements et champs chirurgicaux - Exigences et méthodes d'essai - Partie 1 : Champs et casaques chirurgicaux

Operationskleidung und -abdecktücher - Anforderungen und Prüfverfahren - Teil 1: Operationsabdecktücher und -mäntel

This European Standard was approved by CEN on 29 December 2024.

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European foreword

This document (EN 13795-1:2025) has been prepared by Technical Committee CEN/TC 205 “Non-active medical devices”, the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by July 2025, and conflicting national standards shall be withdrawn at the latest by July 2025.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 13795-1:2019.

EN 13795-1:2025 includes the following significant technical changes with respect to EN 13795-1:2019:

a) clarification of testing specifications and reporting of results;

b) preparation of samples for testing of bursting strength in the wet state according to the test method standard EN ISO 13938-1:2019 (i.e. not any longer according to EN 29073-3:1992 as in the previous version);

c) expansion of former Annex D “Environmental aspects” to include considerations regarding environmental impact and circular economy (now Annex D “Environmental impact”);

d) alignment with Regulation (EU) 2017/745 (including updated Annex ZA);

e) update of normative references and bibliography.

This document has been prepared under a standardization request addressed to CEN by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

For the relationship with EU Legislation, see informative Annex ZA, which is an integral part of this document.

EN 13795 consists of the following parts, under the general title *Surgical clothing and drapes — Requirements and test methods*:

— *Part 1: Surgical drapes and gowns*;

— *Part 2: Clean air suits*.

Any feedback and questions on this document should be directed to the users’ national standards body. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

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Introduction

The transmission of infective agents during invasive surgical procedures can occur in several ways (see informative Annex B).

Surgical drapes, including the intended use as a sterile field, and surgical gowns are used to minimize the spread of infective agents to and from patients' operating wounds, thereby helping to prevent post-operative wound infections (see Annex B).

The performance required of coverings for patients, clinical staff and equipment varies with, for example, the type and duration of the procedure, the degree of wetness of the operation field, the degree of mechanical stress on the materials and the susceptibility of the patient to infection.

The use of surgical gowns with resistance to the penetration of liquids can also diminish the risk to the operating staff from infective agents carried in blood or body fluids.

This document is intended to assist the communication between manufacturers and third parties with regard to material or product characteristics and performance requirements.

Therefore, Annex B provides comprehensive information on characteristics, measurement of performance and performance requirements. Annex C provides information on characteristics regarded relevant in context with surgical gowns and drapes, however but not covered normatively (i.e. without applicable performance requirements). Annex D includes considerations regarding environmental impact and circular economy. Annex E explains the concept of performance levels and provides guidance to users for selecting products.

This document focuses on General Safety and Performance Requirements (GSPR) arising from the Medical Device Regulation (EU) 2017/745, which are applicable to surgical drapes and gowns. The requirements and guidance in this document are expected to be of help to manufacturers and users when designing, processing, assessing and selecting products. It is the intention of this document to ensure the same level of safety from single-use and reusable surgical clothing and drapes throughout their useful life.

Surgical gowns are used to minimize the transmission of infective agents between patients and clinical staff during surgical and other invasive procedures. Hereby, surgical gowns contribute to the clinical condition and the safety of patients as well as to the safety and health of users following up General Safety and Performance Requirements (GSPR) of Regulation (EU) 2017/745 on Medical Devices. This document addresses the same level of protection for patients and users (i.e. the surgical team) by not differentiating the performance requirements for surgical gowns respectively. However, this document does not formally address any Essential Health and Safety Requirements of Regulation (EU) 2016/425 on Personal Protective Equipment and does not provide specific guidance for surgical gowns intended by the manufacturer for dual use as medical device and personal protective equipment.

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1 Scope

This document specifies information to be supplied to users and third-party verifiers in addition to the usual labelling of medical devices (see EN ISO 20417 and EN ISO 15223-1) concerning manufacturing and processing requirements.

This document gives information on the characteristics of single-use and reusable surgical gowns and surgical drapes used as medical devices for patients, clinical staff and equipment, intended to prevent the transmission of infective agents between clinical staff and patients during surgical and other invasive procedures.

This document specifies test methods for evaluating the identified characteristics of surgical drapes and gowns and sets performance requirements for these products.

This document does not include information on resistance to penetration by laser radiation of products.

NOTE If resistance to penetration by laser radiation is claimed for surgical drapes, suitable test methods together with an appropriate classification system are given in EN ISO 11810.

This document does not cover requirements for incision drapes or films.

This document does not cover requirements for antimicrobial treatments for surgical gowns and drapes. Antimicrobial treatment can cause environmental risks such as resistance and pollution. However, antimicrobial treated surgical gowns and drapes fall under the scope of this document with respect to their use as surgical gowns and drapes.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN ISO 139:2005,[1] *Textiles — Standard atmospheres for conditioning and testing (ISO 139:2005)*

EN ISO 811:2018, *Textiles — Determination of resistance to water penetration — Hydrostatic pressure test (ISO 811:2018)*

EN ISO 9073-3:2023, *Nonwovens — Test methods — Part 3: Determination of tensile strength and elongation at break using the strip method (ISO 9073-3:2023)*

EN ISO 9073-10:2004, *Textiles — Test methods for nonwovens — Part 10: Lint and other particles generation in the dry state (ISO 9073-10:2003)*

EN ISO 10993-1:2020, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018, including corrected version 2018-10)*

EN ISO 11737-1:2018,[2] *Sterilization of medical devices — Microbiological methods — Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018)*

EN ISO 13938-1:2019, *Textiles — Bursting properties of fabrics — Part 1: Hydraulic method for determination of bursting strength and bursting distension (ISO 13938-1:2019)*

[1] As impacted by EN ISO 139:2005/A1:2011.

[2] As impacted by EN ISO 11737-1:2018/A1:2021.